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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,853	01/17/2002	Alan E. Kligerman	7706-232U1	1619

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,853	KLIGERMAN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *3,4,9,10,13-17,19-21 and 24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,11,12,18,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5&6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 32-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

2. Applicant's election with traverse of invention group I, claim 1-31 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that all the inventions are classified in the same class and subclass. This is not found persuasive because being in the same class and subclass does not necessarily mean the claimed subject matters are not patentably distinct. The claimed subject matters are distinct from each other as discussed in the prior office action. Further, the searches of the inventions are not limited to patent literature.

The requirement is still deemed proper and is therefore made FINAL.

Species Election

Claims 1-35 are generic to a plurality of disclosed patentably distinct species comprising: various intestinal or genito-urinary tract disorders. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with William Schwartze on October 9, 2003 a provisional election was made with traverse to prosecute the species of interstitial cystitis.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 4, 9, 10, 13-17, 19-21, 24-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The claims have been examined insofar as they read on elected invention and species.

Claim Rejections 35 U.S.C. 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 2, 5-8, 11, 12, 18, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for interdicting, palliating or alleviating interstitial cystitis, does not reasonably provide enablement for preventing interstitial cystitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are directed to a method of treating or preventing interstitial cystitis. The specification discloses how the method may be useful for suppressing or alleviating the symptoms of interstitial cystitis (page 7). However, the specification fails to adequately teach how to use the method to prevent interstitial cystitis. Interstitial cystitis is characterized by urinary urgency, and frequency and supra-pubic pain not caused by some well-known conditions, its etiology is largely unknown. See, Myers "Diagnosing Interstitial cystitis in women," (IDS). Applicants have not provided any convincing evidence that their claimed invention is indeed useful as preventive for interstitial cystitis, and have not provided sufficient guidance to allow

one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 5-8, 11, 12, 18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al (IDS, D7), or Whitmore et al. (IDS, E7), or Jones (IDS, D16), and in further view of ~~Tadaaki~~ Inoue et al. (US 5,674,527).

4. Tu teaches the usefulness of a commercially available glycerophosphate salt (calcium) composition (Prelief) for treating interstitial cystitis. See the entire document.

5. Tu do no teach the employment of other salt of glycerophosphate for treating interstitial cystitis.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ a composition comprising a glycerophosphate salt, wherein the cation is potassium, magnesium, or sodium.

A person of ordinary skill in the art would have been motivated to employ a composition comprising a glycerophosphate salt, wherein the cation is potassium, magnesium, or sodium because, as shown in ~~Tadaaki~~ Inoue et al., that calcium may be provide by salt other than glycerophosphate, and glycerophosphate such as potassium, magnesium or sodium salt may be

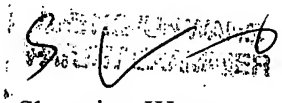
used for providing glycerophosphate anion. See, particularly, column 4, lines 19-35. Therefore, being not employing the particular salt disclosed in the prior art is seen to be an obvious variation from the known method. The optimization of a result effective parameter, e.g., effective amount, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner



Shengjun Wang

October 10, 2003